



510(k) Summary
V Series Monitoring System Monitoring System

This 510(k) Summary is provided in accordance with the requirements of 21 CFR 807.92

Date: June 28, 2013

Submitter: Mindray DS USA, Inc.
800 Mac Arthur Blvd
Mahwah, New Jersey 07430

Contact: Russell Olsen
Vice President, Quality and Regulatory Affairs
Telephone: 201.995.8391
Facsimile: 201.995.8605

Device Trade Name: V Series Monitoring System

Common Name: Multi-Parameter Patient Monitor (with arrhythmia detection or alarms)

Device Classification: Primary:

§870.1025- MHX - Physiological, Patient Monitor, with Arrhythmia Detector or Alarms

Secondary:

§870.1025- DSI - Arrhythmia Detector and Alarm
§870.1025- MLD - ST Segment with Alarm Monitor
§870.1110- DSK- Blood Pressure Computer
§870.1130- DXN - Non-invasive Blood Pressure Measurement System
§868.1400- CCK - Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase
§868.1500- NHO/CBQ/NHQ/NHP - Enflurane Gas Analyzer
§868.1620- CBS - Halothane Gas Analyzer
§868.1700- CBR - Nitrous Oxide Gas Analyzer
§868.1720- CCL - Oxygen Gas Analyzer
§870.1425- DQK - Programmable Diagnostic Computer
§870.2300- DRT - Cardiac Monitor (Incl. Cardiachometer and Rate Alarm)
§870.2700- DQA- Oximeter Sensor
§870.2700- MUD- Oximeter, Tissue Saturation
§880.2910- FLL - Clinical Electronic Thermometer
§870.1435- DXG - Single-function, Pre-programmed Diagnostic Computer
§822.1620- GWM- Intracranial Pressure Monitoring Device

Predicate Device: Endeavour Monitoring System/K102004

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Device Description: The V Series Monitoring System is a multi physiological parameter patient monitor. It is a modular system that allows the user to customize monitored parameters based on a patient's need or acuity level.

Indications for Use: The V Series Monitoring System is intended for intra hospital use under the direct supervision of a licensed healthcare practitioner. The Indications for Use for the V Series Monitoring System include the monitoring of the following human physiological parameters:

- ECG waveform derived from 3, 5, 6 and 12 lead measurements
- Heart Rate
- Pulse Oximetry (SpO₂)
- ST Segment Analysis
- Arrhythmia Detection
- Non Invasive Blood Pressure (NIBP)
- Invasive Blood Pressure (IBP)
- Cardiac Output (CO)
- Respiratory Gasses
- Respiration Rate
- Temperature

The V Series Monitoring System has the capability of performing IV Drug and Hemodynamic Calculations and interfacing with network devices. The target populations are adult, pediatric and neonate with the exception of:

- Arrhythmia detection and ST Segment Analysis, for which the target populations are adult and pediatric only,
- IV Drug Calculations for which the target population is adult only, and
- Cardiac Output for which the target population is adult and pediatric only.

The V Series utilizes the following modules for measuring the indicated parameters:

- VPS Module (multi parameter including 3/5/6/12 lead ECG, respiration, pulse oxymetry temperature, non invasive blood pressure and invasive blood pressure)
- Temperature Module
- Invasive Blood Pressure Module
- Cardiac Output Module
- Respiratory Gas Module

**Technological
Comparison to
Predicate Device:**

The V Series Monitoring System is equivalent to predicated device respecting indications for use, basic operation, performance specifications and energy supply.

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The V Series Monitoring System incorporates the new features and non significant system updates relative to the predicate:

- Alarm Watch
- Remote View
- VAccess
- Additional channels for monitoring invasive blood pressure
- Additional channels for monitoring temperature
- Addition of alternate vendor (Masimo) SpO₂
- Addition of a serial port V Device Integrator
- CO₂ calibration
- Module Status Dialogue
- Connectivity to eGateway
- Pulmonary Artery Insertion Display
- Graphic Trends
- ECG Full Disclosure
- Events tab
- Clearing patient history without discharge
- Interface to Camino Intracranial Pressure Monitor
- Interface to Vigilance/ Vigilance II/Vigileo/EV1000 Monitor
- VPS Synchronization
- 21" Display
- External Module Rack
- Strip Recorder Module
- Interface to Mindray Gas Module III
- Interface to INVOS 5100C Cerebral/Somatic Oximeter
- 12 Lead ECG Interpretation

**Summary of
Performance
Testing:**

The V Series Monitoring System has been tested and found to be in compliance with the following recognized performance, safety and electromagnetic compatibility standards:

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|------------------------------------|--|
| IEC 60601-1:1988 +A1:1991 +A2:1995 | Medical electrical Equipment — General Requirements for Safety |
| IEC 60601-1-1:2000 | Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems |
| IEC 60601-1-2:2007 | Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests |

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| IEC 60601-1-4:1996 + A1:1999 | Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems |
| IEC 60601-2-34:2000 | Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment |
| IEC 60601-1-8:2003 + A1 :2006 | Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems |
| IEC 60601-2-27:2005 | Medical electrical equipment, Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment |
| IEC 60601-2-25:1993 + A1:1999 | Medical electrical equipment, Part 2: Particular requirements for the safety of electrocardiographs |
| IEC 60601-2-30:1999 | Medical electrical equipment, Part 2: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment. |
| ISO 10993-1:2003 | Biological evaluation of medical devices - Part 1: Evaluation and testing. |
| ISO 15223: 2000 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied |
| ISO 14971:2007 | Medical devices -- Application of risk management to medical devices |
| ISO 9919:2005 | Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use |
| ANSPAAMI SP10:2002 + A1:2003 + A2:2006 | Manual, electronic or automated sphygmomanometers |
| ASTM E1112-00 (2006) | Standard Specification for Electronic Thermometers for Intermittent Determination of Patient Temperature |
| EC13: 2002/(R)2007 | Cardiac monitors, heart rate meters, and alarms |
| EC11:1991/(R)2007 | Diagnostic electrocardiographic devices |
| EC57:1998/(R)2003 | Testing and Reporting Performance Results of Cardiac Rhythm and ST-Segment Measurement Algorithms |

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| EN ISO 21647:2004 + Cor 2006 | Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors |
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Summary of

Clinical Testing:

No clinical testing was required to confirm the safety and performance of the new features and non significant modification subject to this 510(k) submission.

Conclusion:

Technological comparison of the V Series Monitoring System relative to the predicate device, compliance with applicable performance, safety and electromagnetic compatibility standards, the V Series Monitoring System shall be considered substantially equivalent to the legally marketed predicate device (Endeavour Monitoring System / K102004).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

December 20, 2013

Mindray DS USA, Inc.
Mr. Russell Olsen
Vice President, Quality and Regulatory Affairs
800 Macarthur Blvd
Mahwah, NJ 07430

Re: K132026

Trade/Device Name: V Series Monitoring System, 12.1" DCU/V12 and 21.0" DCU/V21
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (With Arrhythmia Detection Or Alarms)
Regulatory Class: Class II (two)
Product Code: MHX, DSI, MLD, DSK, DXN, CCK, NHO, CBQ, NHQ, NHP, CBS, CBR, CCL, DQK, DRT, DQA, MUD, FLL, DXG, GWM
Dated: November 8, 2013
Received: November 12, 2013

Dear Mr. Russell Olsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: V Series Monitoring System

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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 Digitally signed by Owen P. Faris
Date: 2013.12.20 14:28:24 -0500

Indications for Use (continued):

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- VPS Module (multi parameter including 3/5/6/12 lead ECG, respiration, pulse oxymetry temperature, non invasive blood pressure and invasive blood pressure)
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